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EXAMINER

APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/624,532	Applicant(s) JANG ET AL.	
	Examiner Michael Apanius	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19, 24, 28-45, 50, 51 and 53-67 is/are pending in the application.
- 4a) Of the above claim(s) 2, 7, 9, 11, 16, 28-45, 50, 51 and 61-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 8, 10, 12-15, 17, 19, 24 and 53-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment filed on 8/14/2006. The amendment is entered. The amendment to claim 1 is acknowledged. Currently, claims 1-17, 19, 24, 28-45, 50, 51 and 53-67 are pending, while claims 2, 7, 9, 11, 16, 28-45, 50, 51 and 61-67 remain withdrawn from consideration.

Drawings

2. Upon further consideration, the drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the combined limitations of claim 14 must be shown in the same embodiment or the feature(s) canceled from the claim(s). It is respectfully submitted that the new figure 7 is redundant and fails to show two electrode distance adjusters that are separated from each other by a predetermined distance and are perpendicular to each other, as set forth in claim 13. No new matter should be entered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief

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description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3-6, 8, 10, 12-15, 17, 19, 24 and 53-60 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although the original disclosure appears to provide support for supplying a constant current regardless of a load (i.e. see original claim 1 and paragraph 48), the original disclosure does not appear to provide sufficient support for supplying a direct current as recited in amended claim 1. Therefore, the amendment to claim 1 introduces new matter into the claims because it now recites a "direct current".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4, 6, 8, 10 and 53-59 rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman (US Patent No. 6,408,204) in view of Pacela (US Patent No. 3,871,359).

7. Regarding claim 1, Hirschman discloses an impedance measurement system for measuring skin impedance in a small skin region, comprising an electrode unit (figure 4) having current supply electrodes (52a and 52d) and measurement electrodes (54b and 54c), and a current source (column 6, lines 60-61). The skin impedance is obtained from a measured response signal.

8. Regarding claims 53-59, Hirschman discloses that opposing first and second measurement electrodes are located between opposing first and second current supply electrodes. Hirschman further discloses that the electrodes can have the same complimentary open two-dimensional shape (column 8, lines 34-37).

9. Regarding claims 4, 6, 8 and 10, the measurement electrodes are disposed perpendicular to the current supply electrodes.

10. Hirschman appears to be silent concerning whether or not the current source is capable of supplying a constant current to the current supply electrodes. However,

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Hirschman discloses that in conventional impedance plethysmography a constant current source (15) of RF energy is used (column 5, lines 57-60).

11. It would have been obvious to one having ordinary skill in the art at the time of invention to have used a constant current source of RF current in the system of Hirschman because constant current sources are well-known and routinely applied within the art.

12. Hirschman does not expressly disclose supplying a direct current.

13. Pacela teaches that it is well known to use either alternating current or direct current in bioelectrical impedance measurements (paragraph bridging columns 1 and 2). Despite the fact that Pacela states that direct current is only infrequently used due to the possibility of the increased hazard of an electrical shock, Pacela notes that direct current is used, well known and established in the art.

14. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the constant current of Hirschman to be a direct current, as taught by Pacela and as is well known in the art, instead of alternating current because it is routine within the art to apply alternative known currents.

15. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman (US Patent No. 6,408,204) as modified by Pacela (US Patent No. 3,871,359) as applied to claims 1, 4, 6, 8, 10 and 53-59 above, and further in view of Hagen et al. (US Patent No. 5,114,424).

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16. Hirschman as modified by Pacela meets the limitations of claims 1, 4, 6, 8, 10 and 53-59 as stated above.

17. Regarding claims 3 and 5, although Hirschman discloses that the electrodes can have any suitable configuration (column 8, lines 34-37), he does not expressly disclose an angular shape.

18. Hagen et al. teaches alternative angular open two-dimensional electrodes which face one another (14 and 15 in figure 3) that can be used in impedance measurements (column 4, lines 42-43).

19. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the angular electrode shape taught by Hagen et al. as an alternative electrode shape in the system of Hirschman as modified by Pacela.

20. Claims 1, 15, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher et al. (US Patent No. 3,957,037) in view of Pacela (US Patent No. 3,871,359).

21. Regarding claim 1, Fletcher et al. discloses an impedance measurement system for measuring skin impedance in a small skin region, comprising an electrode unit having current supply electrodes (the two outside electrodes of figure 1) and measurement electrodes (the two inside electrodes of figure 1), and a current source (12). Note that the current source may be constructed from a "constant current generator" (column 3, lines 51-53) that is capable of supplying a constant alternating current. The skin impedance is obtained from a measured response signal.

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22. Regarding claim 15, the system has electrode distance adjusters (figure 2) for adjusting the distance between the electrodes.

23. Regarding claim 53, the measurement electrodes are disposed between the current supply electrodes (see arrangement in figure 1).

24. Regarding claim 54, the current supply electrodes comprise two electrodes opposite one another.

25. Fletcher et al. does not expressly disclose supplying a direct current.

26. Pacela teaches that it is well known to use either alternating current or direct current in tetrapolar bioelectrical impedance measurements (paragraph bridging columns 1 and 2).

27. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the constant current of Fletcher et al. to be a direct current, as taught by Pacela and as is well known in the art, instead of alternating current because it is routine within the art to apply alternative known currents.

28. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher et al. (US Patent No. 3,957,037) as modified by Pacela (US Patent No. 3,871,359), as applied to claims 1, 15, 53 and 54 above, and further in view of Hofmann (US Patent No. 5,810,762).

29. Fletcher et al. discloses electrode distance adjusters but does not expressly disclose an adjuster having the structure set forth in claim 14.

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30. Hofmann teaches an electrode distance adjuster (figure 9) including a stationary screw line (140), a rotary screw (150), and fixing studs (152 and 154).

31. It would have been obvious to one having ordinary skill in the art at the time of invention to have used the electrode distance adjuster taught by Hofmann in the system of Fletcher et al. as modified by Pacela because the adjusters are art-recognized alternatives that perform the same function of adjusting the distance between electrodes and because it is routine in the art to substitute equivalent parts.

32. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Libke et al. (US Patent No. 4,895,163) in view of Pacela (US Patent No. 3,871,359).

33. Libke et al. discloses an impedance measurement system for measuring skin impedance in a small skin region, comprising an electrode unit having current supply electrodes (12 and 16) and measurement electrodes (10 and 14), and a current source. Note that Libke et al. states that the current source maintains a test signal and that the current source remains constant (column 6, lines 12-26). Therefore, the current source is at least capable of maintaining a constant alternating current through the current supply electrodes. The skin impedance is obtained from a measured response signal.

34. Libke et al. does not expressly disclose supplying a direct current.

35. Pacela teaches that it is well known to use either alternating current or direct current in tetrapolar bioelectrical impedance measurements (paragraph bridging columns 1 and 2).

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36. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the constant current of Libke et al. to be a direct current, as taught by Pacela and as is well known in the art, instead of alternating current because it is routine within the art to apply alternative known currents.

37. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Libke et al. (US Patent No. 4,895,163) as modified by Pacela (US Patent No. 3,871,359) as applied to claim 1 above, and further in view of Dufresne et al. (US Patent No. 4,917,093).

38. Libke et al. further discloses that the current source has an input unit (figure 5), an external power supply (9V battery in figure 5), a current converter (in figure 3), and an output unit (left side of figure 4).

39. Libke et al. does not expressly disclose a current intensity controller.

40. Dufresne et al. teaches a current intensity controller that uses a variable resistor (column 7, lines 40-43, 132 in figure 4) for the purpose of improving battery life (column 2, lines 29-32).

41. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a current intensity controller as taught by Dufresne et al. in the system of Libke et al. as modified by Pacela in order to improve battery life.

42. Claims 1 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallup et al. (US Patent No. 5,372,141) in view of Pacela (US Patent No. 3,871,359).

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43. Regarding claim 1, Gallup discloses an impedance measurement system for measuring skin impedance in a small skin region, comprising an electrode unit (column 4, lines 7-22) having current supply electrodes and measurement electrodes, and a current source (44). Note that the current source is a source of substantially constant peak-to-peak alternating current (column 1, lines 50-51) capable of supplying a constant alternating current. The skin impedance is obtained from a measured response signal.

44. Regarding claim 24, the system has an image display unit including a data analyzer (34), a signal conversion unit (62), an operation controller (14), and a display unit (12 and 36).

45. Gallup et al. does not expressly disclose supplying a direct current.

46. Pacela teaches that it is well known to use either alternating current or direct current in tetrapolar bioelectrical impedance measurements (paragraph bridging columns 1 and 2).

47. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the constant current of Gallup et al. to be a direct current, as taught by Pacela and as is well known in the art, instead of alternating current because it is routine within the art to apply alternative known currents.

48. Claims 1 and 60 rejected under 35 U.S.C. 103(a) as being unpatentable over Petrucelli et al. (US 6,292,690) in view of Pacela (US Patent No. 3,871,359).

49. Petrucelli et al. discloses an impedance measurement system for measuring skin impedance in a small skin region, comprising an electrode unit having current supply

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electrodes (21, 22) and measurement electrodes (25, 26), and a current source (11).

The current source supplies a constant current to the current supply electrodes (column 3, lines 66-67). The skin impedance is obtained from a measured response signal.

50. Regarding claim 60, a signal processing unit (70) which is connected to the electrodes, receives response signals, generates a potential difference signal, removes noise, and amplifies (column 4, lines 26-51).

51. Petrucelli et al. does not expressly disclose supplying a direct current.

52. Pacela teaches that it is well known to use either alternating current or direct current in tetrapolar bioelectrical impedance measurements (paragraph bridging columns 1 and 2).

53. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the constant current of Petrucelli et al. to be a direct current, as taught by Pacela and as is well known in the art, instead of alternating current because it is routine within the art to apply alternative known currents.

54. Claims 1, 19 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mee et al. (US Patent No. 4,578,635) in view of Petrucelli et al. (US 6,292,690) and Pacela (US Patent No. 3,871,359).

55. Mee et al. discloses an impedance measurement system having measurement electrodes (2), and a signal processing unit (column 7, line 47 - column 8, line 60) comprising a buffer (A1 in figure 2), a potential difference measurer (1), a combined offset voltage controller and amplifier (A2), and a phase inverter amplifier (A3).

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56. Mee et al. does not expressly disclose current supply electrodes, a current source, or a filter or a constant direct current.

57. Petrucelli et al. teaches current supply electrodes (21, 22) connected to a current source (11) capable of supplying a constant alternating current and a signal processing unit which includes a filter (column 4, lines 38-42) for the purpose of removing noise and measuring body impedance.

58. It would have been obvious to one having ordinary skill in the art at the time of invention to have used current supply electrodes, a current source and a filter as taught by Petrucelli et al. in the system of Mee et al. in order to remove noise and measure body impedance.

59. Pacela teaches that it is well known to use either alternating current or direct current in tetrapolar bioelectrical impedance measurements (paragraph bridging columns 1 and 2).

60. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the constant current of Mee et al. as modified by Petrucelli et al. to be a direct current, as taught by Pacela and as is well known in the art, instead of alternating current because it is routine within the art to apply alternative known currents.

61. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuo (US 2003/0176808) in view of Pacela (US Patent No. 3,871,359).

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62. Regarding claim 1, Masuo discloses an impedance measurement system for measuring skin impedance in a small skin region, comprising an electrode unit having current supply electrodes (1a and 1b in figure 1) and measurement electrodes (2a and 2b), and a current source (3). Note that the current source supplies a constant radio frequency current (abstract). The skin impedance is obtained from a measured response signal.

63. Pacela teaches that it is well known to use either alternating current or direct current in tetrapolar bioelectrical impedance measurements (paragraph bridging columns 1 and 2).

64. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the constant current of Masuo to be a direct current, as taught by Pacela and as is well known in the art, instead of alternating current because it is routine within the art to apply alternative known currents.

65. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuo (US 2003/0176808) as modified by Pacela (US Patent No. 3,871,359), as applied to claim 1 above, and further in view of Fletcher et al. (US Patent No. 3,957,037).

66. Masuo as modified by Pacela does not expressly disclose an electrode distance adjuster.

67. Fletcher et al. discloses electrode distance adjusters for the purpose of simplifying electrode positioning and allowing the electrodes to be adjusted to fit different body segments.

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68. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used an electrode distance adjuster as taught by Fletcher for either the current supply electrodes or the measurement electrodes of Masuo as modified by Pacela in order to simplify electrode positioning and allow the electrodes to be adjusted to fit different body segment.

69. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuo (US 2003/0176808) as modified by Pacela (US Patent No. 3,871,359) and Fletcher et al. (US Patent No. 3,957,037), as applied to claim 15 above, and further in view of Hofmann (US 5,810,762).

70. Masuo as modified by Pacela and Fletcher et al. does not expressly disclose an adjuster having the structure set forth in claims 12 and 14.

71. Hofmann teaches an electrode distance adjuster (figure 9) including a stationary screw line (140), a rotary screw (150), and fixing studs (152 and 154).

72. It would have been obvious to one having ordinary skill in the art at the time of invention to have used the electrode distance adjuster taught by Hofmann in the system of Masuo as modified by Pacela and Fletcher because the adjusters are art-recognized alternatives that perform the same function of adjusting the distance between electrodes and because it is routine in the art to substitute equivalent parts.

Response to Arguments

73. Applicant argues, with respect to claim 1, that Fletcher does not state that the output of the high frequency generator is a constant current. However, it is respectfully submitted that the high frequency generator is capable of outputting a constant current because it is constructed from a constant current generator.

74. Applicant argues, with respect to claim 17, that one of ordinary skill in the art would not be motivated to modify the Libke system, which is intended to be undetectable to the subject, so as to provide a high voltage signal capable of inducing muscle contractions, as provided by the Dufresne system. However, it is respectfully submitted that the motivation of saving power is common among all electrically powered systems. Therefore, there is sufficient motivation to combine the power saving teachings of Dufresne with the system of Libke.

75. Applicant argues, with respect to claims 12-14, that Fletcher does not provide distance adjusters for current supply electrodes and that neither Fletcher nor Hofman, alone or in combination, suggests two distance adjusters that are perpendicular and separated from each other by a predetermined distance. These argument are moot in view of the new rejections noted above. In regards to the new rejection combining Masuo, Pacela and Fletcher, it is noted that it would have been obvious to one having ordinary skill in the art to apply the electrode distance adjuster of Fletcher to either the current-supply electrodes or the measurement electrodes of Masuo as modified by Pacela. It is clearly apparent that the motivation of simplifying electrode positioning and

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allowing electrodes to be adjustable to fit different body segments is equally applicable to current supply electrodes and measurement electrodes.

76. Applicant's arguments, with respect to amended claim 1, that the applied references do not disclose a direct current have been considered but are moot in view of the new ground(s) of rejection.

77. Applicant's arguments, with respect to claim 1, that Skladnev does not disclose a constant current have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

78. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson (US Patent No. 3,784,908), Motoyama (US Patent No. 3,971,366) and Ohkura (US 2004/0133121) disclose using direct current in body impedance measurements.

79. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

80. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

81. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

82. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

83. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA


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